February 21, 2007

Carrie E. Houtman
Toxicology Consulting
The Dow Chemical Company
1691 North Swede
Midland, MI 48674

Dear Ms. Houtman:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Chlorinated C2 Stream posted on the ChemRTK HPV Challenge Program Web site on January 18, 2005. I commend The Dow Chemical Company for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Dow Chemical advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Mark W. Townsend, Chief
HPV Chemicals Branch

Enclosure

cc: O. Hernandez
C. Augustyniak
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Chlorinated C2 Streams

Summary Of EPA Comments

The sponsor, The Dow Chemical Company, submitted a test plan and robust summaries to EPA for Chlorinated C2 Streams (CAS No. 68411-72-3) dated December 2, 2004. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 18, 2005. Data on 1,1,2,2-tetrachloroethane (CAS No. 79-34-5), used as a representative chemical, are also provided.

EPA has reviewed this submission and has reached the following conclusions:

1. General Comment. The submitter needs to provide a complete compositional analysis of the chlorinated C2 stream specifying the remaining 21% of the components. The submitter also needs to revise the misleading language on OECD SIDS conclusions about the toxicity of 1,1,2,2-tetrachloroethane.

2. Analog Justification. The submitter needs to provide available data on 1,2,2-trichloroethane and other chloroethanes and compare them to 1,1,2,2-tetrachloroethane to support the position that the latter substance will adequately represent other components in chlorinated C2 streams and/or the stream as a whole.

3. Physicochemical Properties and Environmental Fate. EPA disagrees that 1,1,2,2-tetrachloroethane itself represents the Chlorinated C2 Stream for all endpoints. A more reasonable representation of the physicochemical properties and environmental fate of Chlorinated C2 Stream may be obtained by considering all of the possible chlorinated ethane derivatives that may be present in the mixture. The submitter needs to provide this additional information to adequately address all endpoints for the purposes of the HPV Challenge Program.

4. Health Effects. EPA reserves judgement on adequacy of the data submitted for 1,1,2,2-tetrachloroethane to characterize mammalian toxicity of chlorinated C2 stream pending receipt of adequate justification as stated under point 2 above.

5. Ecological Effects. EPA reserves judgement on the adequacy of the data submitted for 1,1,2,2-tetrachloroethane to characterize ecological effects of chlorinated C2 stream pending receipt of adequate justification as stated under point 2 above.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments On The Chlorinated C2 Stream Challenge Submission

General

The submitter states that the chlorinated C2 stream is a “compilation of process intermediate streams....that consists of chlorinated 2-carbon chemicals” with the largest components being 1,1,2,2-tetrachloroethane (approximately 64%) and 1,1,2-trichloroethane (CAS No. 79-00-5, approximately 15%). The remainder of the stream (21%) is composed of a number of chlorinated ethanes “with no single component present at more than a few percent of the total stream.” Given the chemistry of the chlorination process and the likely impurities in the ethane feedstock at various facilities, chlorinated methanes and propanes may also be present in the chlorinated C2 stream. Although the submitter notes that the composition of this substance is “somewhat variable”, the test plan does not provide a typical analysis of the stream so that the importance of each component of the composition can be independently assessed. Such information needs to be included in the test plan.

The submitter's interpretation of the SIAM 15 (October 2002) conclusion for the 1,1,2,2-tetrachloroethane case is misleading. The SIAM 15 recommendation for "low priority for further work" is based on low exposure potential and not a lack of concern about its toxicological properties. The submitter needs to revise the statement to accurately represent the conclusions of the OECD SIDS assessment.

Analog Justification

The submitter proposes to use data on the major component of the mixture, 1,1,2,2-tetrachloroethane, to represent the toxicological properties of the chlorinated C2 stream because of "its high volume percent of the stream and its mammalian and environmental toxicity." The submitter states that the "overall mammalian and environmental toxicity" is either similar to or greater than that of the next most abundant component in the mixture, 1,1,2-trichloroethane, with the "possible exception of acute oral toxicity." Although not explicitly stated by the submitter, EPA assumes that this statement also is meant to apply to the other chlorinated ethanes in the mixture besides 1,1,2-trichloroethane. Further, the submitter uses measured data and estimated values obtained for 1,1,2,2-tetrachloroethane to represent the physicochemical and environmental fate endpoints of chlorinated C2 stream. Given that the sponsored substance is a mixture, it is expected that the physicochemical endpoints for the substance will be characterized by a range of values instead of by a single value from one of the components in the mixture.

The submitter provides no data to support using 1,1,2,2-tetrachloroethane as an analog except for the Dow Chemical Company Industrial Hygiene Guideline for 1,1,2,2-tetrachloroethane in the test plan. To adequately justify the use of 1,1,2,2-tetrachloroethane as an analog of the chlorinated C2 stream, the submitter needs to provide available data on 1,1,2-trichloroethane and other chloroethanes, compare them with 1,1,2,2-tetrachloroethane, and show why the selected analog will represent other components in the stream and the stream as a whole.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

EPA agrees that there are sufficient data for the following endpoints for 1,1,2,2-tetrachloroethane: melting point, boiling point, vapor pressure, water solubility, and partition coefficient. While 1,1,2,2-tetrachloro-ethane comprises the majority of the Chlorinated C2 Stream, EPA disagrees that 1,1,2,2-tetrachloro-ethane itself is an adequate surrogate for the Chlorinated C2 Stream for all endpoints. A more reasonable representation of the physicochemical properties of Chlorinated C2 Stream may be obtained by considering all of the possible chlorinated ethane derivatives that may be present in the mixture. All these derivatives, with the exception of hexachloroethane, have melting points < 0 ºC; therefore, the melting point of the mixture is likely to be below 0 ºC. EPA does not require a measured value for melting points above 0 ºC. In addition, boiling point, vapor pressure, water solubility, and log K_{ow} values for the various chlorinated ethane derivatives are not adequately represented by 1,1,2,2-tetra-chloroethane alone. Since the Chlorinated C2 Stream mixture will not have sharply defined physicochemical properties, it is reasonable to use the range of the properties of the components of the mixture to represent the substance. EPA was able to obtain physicochemical data for the various chlorinated ethane derivatives from the available literature, the PHYSPROP database (2005), HSDB (2005), and EPA estimation methods; therefore, no additional testing is recommended. The submitter needs to provide this additional information in appropriate summaries to adequately address these endpoints for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

EPA agrees that, for 1,1,2,2-tetrachloroethane, there are sufficient data for the following endpoints: biodegradation, fugacity, stability in water, and photodegradation. While this substance comprises the majority of the Chlorinated C2 Stream, EPA disagrees that 1,1,2,2-tetrachloroethane itself provides a reasonable surrogate for the Chlorinated C2 Stream. A more reasonable representation of the

environmental fate properties of Chlorinated C2 Stream may be obtained by considering all of the possible chlorinated ethane derivatives that may be present in the mixture. EPA was able to obtain environmental fate data for the various chlorinated ethane derivatives from the available literature, the PHYSPROP database (2005), HSDB (2005), and EPA estimation methods. In general, all of the chlorinated ethane derivatives appeared to behave similarly in biodegradation tests, so that use of a representative substance for this endpoint appears reasonable. The data for photodegradation, stability in water, and fugacity for the various chlorinated ethane derivatives were not adequately represented by 1,1,2,2-tetrachloroethane alone. Since the Chlorinated C2 Stream will not have neatly defined behavior in the environment, it is reasonable to use the range of the properties of the components of the mixture to represent the substance for these three endpoints.

While no additional fate testing is recommended, the submitter needs to provide the additional available information in appropriate summaries to adequately address all environmental fate endpoints for the purposes of the HPV Challenge Program.

Health Effects

No data are provided on the chlorinated C2 stream. Although limited data are available for 1,1,2,2-tetra-chloroethane for all health effects endpoints, the submitter needs to provide adequate justification to demonstrate that data for 1,1,2,2-tetrachloroethane are independently sufficient to characterize the toxicity of the mixture of the chemicals in the chlorinated C2 stream. Until such information is received, EPA reserves judgement on the adequacy of the data submitted for 1,1,2,2-tetrachloroethane to characterize mammalian toxicity of other components in the stream and of the stream as a whole.

In addition, no data were submitted for other significant components of the chlorinated C2 stream such as 1,1,2-trichloroethane, the second largest component (approximately 15%), and the remaining components of the chlorinated C2 stream. Such data are essential in conducting an independent evaluation of the toxicity of the sponsored chlorinated C2 stream .

Ecological Effects (fish, invertebrates, and algae).

EPA reserves judgement on the adequacy of the data submitted for 1,1,2,2-tetrachloroethane to characterize ecological effects of the chlorinated C2 stream pending receipt of adequate justification.

Specific Comments on the Robust Summaries

EPA will provide comments on the Robust Summaries following receipt of the revised submission.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.